K021285

MAY 02 2002

510(k) Summary

1. **Device Name:** HI-TORQUE Guide Wire
   - HI-TORQUE BALANCED MIDDLEWEIGHT (BMW), Model 6720
   - HI-TORQUE BALANCED HEAVYWEIGHT (BHW), Model 6722
   - HI-TORQUE BALANCED TREK, Model 6723
   - HI-TORQUE EXTRA S'PORT, Model 6724
   - HI-TORQUE IRON MAN, Model 6725
   - HI-TORQUE WHISPER LS, Model 6726
   - HI-TORQUE WHISPER MS, Model 6737

2. **Devices to Which Equivalence is Claimed:** HI-TORQUE BALANCED MIDDLEWEIGHT (**K983033**, cleared 11/10/98) with regard to intended use and all other aspects of the proposed HI-TORQUE Guide Wires are identical to the currently marketed Guide Wires (K950156, cleared 4/5/95; **K963702**, cleared 1/22/97; **K982083**, cleared 9/11/98; **K983033**, cleared 11/10/98; **K991152**, cleared 4/29/99; and **K002206**, cleared 8/24/00).

3. **Intended Use:** The HI-TORQUE Guide Wire is intended for general intravascular use to aid in the selective placement of interventional devices and implantable coronary venous leads in the coronary and/or peripheral vasculature during diagnostic and/or therapeutic procedures.

4. **Device Description:** The HI-TORQUE Guide Wires are steerable guide wires available in a nominal diameter of 0.14".

5. **Summary of Technological Characteristics:** This notification concerns a labeling modification to expand the indications for currently marketed devices. There are no changes to the design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject devices.

6. **Summary of Substantial Equivalence:** This notification concerns a labeling modification to expand the indications for the currently marketed device. The indications are equivalent to the currently marketed HI-TORQUE BALANCED MIDDLEWEIGHT (**K983033**, cleared 11/10/98). All other aspects of the proposed Guide Wires are identical to the currently marketed Guide Wires (**K950156**, cleared 4/5/95; **K963702**, cleared 1/22/97; **K982083**, cleared 9/11/98; **K983033**, cleared 11/10/98; **K991152**, cleared 4/29/99; and **K002206**, cleared 8/24/00).

7. **Testing Data:**

   In Vivo Testing

   Animal studies were conducted to evaluate the performance of the HI-TORQUE Guide Wires when the devices were used within the coronary vein. The results of the

in vivo animal evaluation showed that the Hi-Torque Guide Wires are acceptable within the coronary vein when used with a compatible lead system.

Human Clinical Testing Data:

HI-TORQUE Guide Wires were evaluated in a clinical investigation. The function of the HI-TORQUE Guide Wire in this clinical investigation was to aid in the placement of a coronary venous pace/sense lead in the coronary venous vasculature. The results demonstrated that the HI-TORQUE Guide Wires are safe and effective for use in placing a compatible coronary venous pace/sense lead in the coronary venous vasculature.

8. **Conclusion:** The HI-TORQUE Guide Wires with the expanded indication are substantially equivalent to the currently marketed HI-TORQUE BALANCE MIDDLEWEIGHT Guide Wire (**K983033**, cleared 11/10/98) with regard to intended use. All other aspects of the proposed HI-TORQUE Guide Wires are identical to the currently marketed Guide Wires (**K950156**, cleared 4/5/95; **K963702**, cleared 1/22/97; **K982083**, cleared 9/11/98; **K983033**, cleared 11/10/98; **K991152**, cleared 4/29/99; and **K002206**, cleared 8/24/00).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2002

Ms. Karen S. Alsop
Pr. Regulatory Affairs Associate
Guidant Corporation
4100 Hamline Avenue N
St. Paul, MN 55112

Re: K021282
Trade Name: LV-1 Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold fitting
Regulatory Class: Class II (two)
Product Code: DTL

Re: K021283
Trade Name: Guidant Balloon Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO

Re: K021284
Trade Name: EASYTRAK® Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY

Re: K021285
Trade Name: HI-TORQUE® Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: April 17, 2002
Received: April 18, 2002

Dear Ms. Alsop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include

requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021285

Device Name: HI-TORQUE® BALANCE MIDDLEWEIGHT™ Guide Wire
HI-TORQUE EXTRA S'PORT™ Guide Wire
HI-TORQUE IRON MAN™ Guide Wire
HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire
HI-TORQUE BALANCE TREK™ Guide Wire
HI-TORQUE WHISPER™ LS and MS Guide Wires

Indications for Use:

The HI-TORQUE Guide Wire is intended for general intravascular use to aid in the selective placement of interventional devices and implantable coronary venous leads in the coronary and/or peripheral vasculature during diagnostic and/or therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

for Donna-Bea Tillman

Division of Cardiovascular & Respiratory Devices
510(k) Number _____